

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>785-012474-US (PAR)</b>
INTERNATIONAL APPLICATION NO. <b>PCT/EP04/08792</b>	INTERNATIONAL FILING DATE <b>08 MAY 2004</b>	U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/567,594</b>
TITLE OF INVENTION DOSAGE FORM THAT IS SAFEGUARDED FROM ABUSE		PRIORITY DATE CLAIMED <b>06 AUGUST 2003</b>
APPLICANT(S) FOR DO/EO/US <b>Arkenau-Maric, et al.</b>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p style="margin-left: 20px;">d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p><b>Items 11 to 20 below concern document(s) or information included:</b></p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.26 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p>		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.6)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/567,594		PCT/EP04/08792		785-012474-US (PAR)	
20 Other items or information:					
International Search Report					
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))				\$ 200.00	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				\$ 0	
All other situations				\$200	
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b))				\$ 400.00	
If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				\$ 0	
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority				\$100	
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB				\$400	
All other situations				\$500	
TOTAL OF 21, 22 and 23 =				\$900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$ 130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	36 - 20 =	16	x \$ 50	\$ 800.00	
Independent claims	- 3 =		x \$200	\$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 1830.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by %.					
SUBTOTAL =				\$	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
TOTAL NATIONAL FEE =				\$ 1830.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
TOTAL FEES ENCLOSED =				\$ 1530.00	
Amount to be refunded:				\$	
Amount to be charged				\$	

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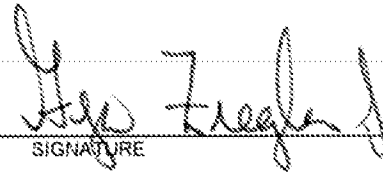
- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 16-1350 in the amount of \$ 1530.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 16-1350. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

**ADVISORY:** If filing by EFS-Web, do NOT attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is not recommended and by doing so your credit card information may be displayed via PAIR. To protect your information, it is recommended paying fees online by using the electronic payment method.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Geza C. Ziegler, Jr.  
Reg. No. 44,004  
Customer No. 2512



SIGNATURE

Geza C. Ziegler, Jr.

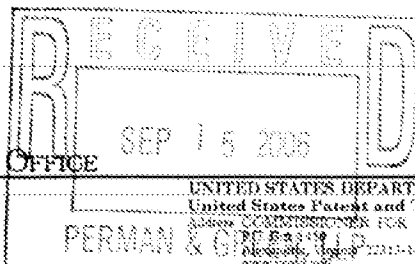
NAME

44,004

REGISTRATION NUMBER



UNITED STATES PATENT AND TRADEMARK OFFICE


 UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address COMMISSIONER FOR PATENTS  
 P.O. Box 319  
 Alexandria, VA 22304-0319  
 www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/567,594	FIRST NAMED APPLICANT Johannes Bartholomaus	ATTY. DOCKET NO. 785012474USPAR
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 2512 **G.A.**  
 PERMAN & GREEN  
 425 POST ROAD  
 FAIRFIELD, CT 06824

 US ACTION  
 DUE DATE 11.12.2006  
 PAPER DATED 9.12.2006  
 OA \_\_\_\_\_ FINAL \_\_\_\_\_  
 MSG PT \_\_\_\_\_ CWS \_\_\_\_\_  
 APPEAL \_\_\_\_\_ ISSUE FEE \_\_\_\_\_  
 OTHER \_\_\_\_\_

INTERNATIONAL APPLICATION NO. PCT/EP04/08792	
I.A. FILING DATE 08/05/2004	PRIORITY DATE 08/06/2003

CONFIRMATION NO. 2497

371 FORMALITIES LETTER



\*OC000000020372206\*

Date Mailed: 09/12/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 02/06/2006
- Copy of the International Search Report filed on 02/06/2006
- Preliminary Amendments filed on 02/06/2006
- Information Disclosure Statements filed on 02/06/2006
- U.S. Basic National Fees filed on 02/06/2006
- Priority Documents filed on 02/06/2006
- Specification filed on 02/06/2006
- Claims filed on 02/06/2006
- Abstracts filed on 02/06/2006
- Drawings filed on 02/06/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$800 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

## SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$1530** for a Large Entity:

- **\$130** Surcharge.
  - The application search fee has not been paid. Applicant must submit **\$400** to complete the search fee. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.
  - The application examination fee has not been paid. Applicant must submit **\$200** to complete the examination fee for a non-small entity. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.
- Total additional claim fee(s) for this application is **\$ 800**
  - **\$800** for **16** total claims over 20.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

FREDERICK SMITH

Telephone: (703) 308-9140 EXT 210

## PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/567,594	PCT/EP04/08792	785012474USPAR